



UNIGLOVES®

EU Declaration of Conformity
according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Medical Device	UNIGLOVES Examination Gloves
Article number	See appendix
Basic UDI-DI according to Annex VI Part C	4260503143710R3
Intended Use	The non-sterile disposable examination gloves are used to protect patients, users or third parties against diseases. The examination gloves can be used in the laboratory, medical and industrial sector as well as in the domestic area by laypersons and health care users.
Risk class according to Annex VIII, Rule 1 und 5	I

Manufacturer	UNIGLOVES Arzt- & Klinikbedarf Handelsgesellschaft mbH Camp-Spich-Str. 71 53842 Troisdorf-Spich Germany
Single Registration Number according to Article 31	Not available yet

We hereby declare on our own responsibility the conformity of the above-mentioned medical devices in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices.

UNIGLOVES Arzt- & Klinikbedarf Handelsgesellschaft mbH hereby declares that medical devices covered by this declaration comply with this Regulation and, where applicable, other relevant Union legislation providing for the drawing up of an EU declaration of conformity.

Conformity for the above medical devices is in accordance with the applicable specifications:

EN 455-1:2000	
EN 455-2:2015	
EN 455-3:2015	Except Unigloves Classic Latex Gloves, Article number 1101 to 1105 (Size XS-XL)
EN 455-4:2009	
Common specification	None

Chosen conformity assessment procedure	Technical File according to annex II und annex III
Validity of this CE declaration of conformity	Valid until 02.06.2022



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Troisdorf, 03.05.2021

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CEO, Sebastian Schuster

Appendix to the Declaration of Conformity

Article number	Description
1101	Unigloves CLASSIC Latexhandschuhe
1102	Unigloves CLASSIC Latexhandschuhe
1103	Unigloves CLASSIC Latexhandschuhe
1104	Unigloves CLASSIC Latexhandschuhe
1105	Unigloves CLASSIC Latexhandschuhe
1921	Unigloves PREMIUM Vinylhandschuhe
1922	Unigloves PREMIUM Vinylhandschuhe
1923	Unigloves PREMIUM Vinylhandschuhe
1924	Unigloves PREMIUM Vinylhandschuhe
1925	Unigloves PREMIUM Vinylhandschuhe
8020	Nitrilhandschuhe SOFT BLUE ECO
8030	Nitrilhandschuhe SOFT BLUE ECO
8040	Nitrilhandschuhe SOFT BLUE ECO
8050	Nitrilhandschuhe SOFT BLUE ECO